

CLAIMS

1. A novel pharmaceutical composition comprising a mixture of higher primary aliphatic
5 alcohols from 24 to 39 carbon atoms from 2 to 99.9% by weight of the composition; at
least one another organic component selected from resins and pigments, hydrocarbons,
esters, ketones and aldehydes, and phenolic compounds from 0.1 to 70% by weight of the
composition, and HMG CoA reductase inhibitor, its salts, analogs or derivatives thereof
substantially devoid of any waxy acid, optionally with pharmaceutically acceptable
10 excipients from 0 to 99.9% by weight of the composition.
2. A composition according to claim 1, wherein the mixture of higher primary aliphatic
alcohols comprises 1-tetracosanol, 1-hexacosanol, 1-heptacosanol, 1-octacosanol, and 1-
triacontanol.
3. A composition according to claims 1 and 2, wherein the mixture of higher primary
15 aliphatic alcohols from 24 to 39 carbon atoms comprising 1-tetracosanol, 1-hexacosanol,
1-heptacosanol, 1-octacosanol, and 1-triacontanol are present as at least 40% by weight of
the composition.
4. A composition according to claims 1-3, wherein the ratio of the mixture of higher primary
aliphatic alcohols and HMG CoA reductase inhibitor, its salts, analogs or derivatives
20 thereof is from 20:1 to 1:20.
5. A composition according to claims 1-4, wherein HMG CoA reductase inhibitor is a statin,
its salts, analogs or derivatives thereof.
6. A composition according to claim 5, wherein the statin is selected from a group
comprising lovastatin, pravastatin, simvastatin, atorvastatin, fluvastatin, rosuvastatin,
25 pitavastatin, or their salts, analogs or derivatives thereof.
7. A composition according to claims 1-6 wherein the pharmaceutically acceptable
excipients are selected from a group comprising diluents, disintegrants, fillers, bulking
agents, vehicles, pH adjusting agents, stabilizers, anti-oxidants, binders, buffers,
lubricants, antiadherants, coating agents, preservatives, emulsifiers, suspending agents,
30 release controlling agents, polymers, colorants, flavoring agents, plasticizers, solvents,

preservatives, glidants, chelating agents and the like; used either alone or in combination thereof.

8. A composition according to claims 1-7, which is formulated as oral dosage forms such as tablets, pills, capsules, gels, finely divided powders, dispersions, suspensions, solutions, emulsions, etc; pulmonary and nasal dosage form such as sprays, aerosols, etc.; topical dosage forms such as gels, ointments, creams, etc; parenteral dosage forms; controlled release formulations; fast melt formulations, lyophilized formulations, delayed release formulations, sustained release, extended release formulations, pulsatile release formulations, and mixed immediate release and controlled release formulations.
9. A process for preparing a pharmaceutical composition according to claim 1 which comprises of the following steps:
- i) isolating the wax,
 - ii) subjecting the wax to extraction with a liquid organic extractant in which primary aliphatic alcohols and other organic components are soluble,
 - iii) recovering said soluble mixture from said extractant,
 - iv) purifying the extract by repeated washing and crystallization,
 - v) drying the extract at temperature below 70°C and making it into a powder form,
 - vi) adding HMG CoA reductase inhibitor, its salts, analogs or derivatives,
 - vii) optionally adding pharmaceutically acceptable excipients and making it into a suitable dosage form.
10. A process according to claim 9, wherein the mixture of higher primary aliphatic alcohols comprises 1-tetracosanol, 1-hexacosanol, 1-heptacosanol, 1-octacosanol, and 1-triacontanol.
11. A process according to claims 9 and 10, wherein the mixture of higher primary aliphatic alcohols from 24 to 39 carbon atoms comprising 1-tetracosanol, 1-hexacosanol, 1-heptacosanol, 1-octacosanol, and 1-triacontanol are present as at least 40% by weight of the composition.

12. A process according to claims 9-11, wherein the ratio of the mixture of higher primary aliphatic alcohols and HMG CoA reductase inhibitor, its salts, analogs or derivatives thereof is from 20:1 to 1:20.
13. A process according to claims 9-12, wherein HMG CoA reductase inhibitor is a statin, its salts, analogs or derivatives thereof.
14. A process according to claim 13, wherein the statin is selected from a group comprising lovastatin, pravastatin, simvastatin, atorvastatin, fluvastatin, rosuvastatin, pitavastatin, or their salts, analogs or derivatives thereof.
15. A method of reducing serum cholesterol level, and treating hyperlipidemia, which comprises administering a composition comprising a mixture of higher primary aliphatic alcohols from 24 to 39 carbon atoms from 2 to 99.9% by weight of the composition; at least one another organic component selected from resins and pigments, hydrocarbons, esters, ketones and aldehydes, and phenolic compounds from 0.1 to 70% by weight of the composition, and HMG CoA reductase inhibitor, its salts, analogs or derivatives thereof, substantially devoid of any waxy acid, optionally with pharmaceutically acceptable excipients from 0 to 99.9% by weight of the composition.
16. Use of a mixture of higher primary aliphatic alcohols from 24 to 39 carbon atoms from 2 to 99.9% by weight of the composition; at least one another organic component selected from resins and pigments, hydrocarbons, esters, ketones and aldehydes, and phenolic compounds from 0.1 to 70% by weight of the composition, and HMG CoA reductase inhibitor, its salts, analogs or derivatives thereof, substantially devoid of any waxy acid, for preparing a composition for reducing serum cholesterol level, and treating hyperlipidemia.
17. A composition comprising a mixture of higher primary aliphatic alcohols from 24 to 39 carbon atoms from 2 to 99.9% by weight of the composition; at least one another organic component selected from resins and pigments, hydrocarbons, esters, ketones and aldehydes, and phenolic compounds from 0.1 to 70% by weight of the composition, and HMG CoA reductase inhibitor, its salts, analogs or derivatives thereof, substantially devoid of any waxy acid, as herein described and illustrated by the examples.

18. The process for the preparation of a composition comprising a mixture of higher primary aliphatic alcohols from 24 to 39 carbon atoms from 2 to 99.9% by weight of the composition; at least one another organic component selected from resins and pigments, hydrocarbons, esters, ketones and aldehydes, and phenolic compounds from 0.1 to 70% by weight of the composition, and HMG CoA reductase inhibitor, its salts, analogs or derivatives thereof, substantially devoid of any waxy acid, as herein described and illustrated by the examples.